

REMARKS

This amendment is responsive to the Office Action mailed January 25, 2007. Applicant submits concurrently herewith: (1) a Request for Continued Examination (RCE) Form; (2) a Petition for Extension of Time; (3) a Petition to Accept a Delayed Claim for Priority; (4) Certified copies of United Kingdom Application Nos. 0219513.9 and 0219514.7; and (5) a Supplemental Information Disclosure Statement.

The specification has been amended to correct the application number of one of the priority United Kingdom patent applications.

Claims 1-12 were pending in the application. In the Office Action mailed January 25, 2007, claims 1-12 have been rejected. In the instant Amendment, claims 2-7 and 12 have been amended, and claims 13-15 have been added. Upon entry of the instant Amendment, claims 1-15 will now be pending in the application.

Claims 2-7 have been amended to correct a grammatical error.

Claim 12 has been amended to spell out MDPI. Support for the amendment is found in the specification at page 3, paragraph [0008].

Claims 13-15 have been added. Support for claim 13 is found, for example, in the specification at page 13, Table 4. Support for claim 14 is found, for example, in the specification at page 11, Table 1. Support for claim 15 is found, for example, in the specification at page 8, paragraph [0040].

Thus, no new matter has been added by these amendments. Entry of the foregoing amendments and consideration of the following remarks are respectfully requested.

Claims 1-12 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 6,737,044 ("*Dickinson*"). This rejection is maintained from a previous Office Action. The Examiner contends that *Dickinson* teaches an aerosol composition comprising a liquid propellant, a first particulate material having an aerodynamic diameter within the range of 0.05 to 11 μm , and a second particulate material comprising particles having a median volume diameter within the range of 15 to 200 μm . The Examiner contends that although *Dickinson* does not teach that up to 96% by weight of lactose particles have a particle size of less than 150 μm , or that up to 25% by weight of lactose particles have a particle size of less than 5 μm , the determination of particular concentrations of particle sizes is within the skill of the ordinary worker as part of the process of normal optimization to achieve the dry powder of the presently claimed composition. Applicant respectfully submits that claims 1-12 would not have been obvious in view of *Dickinson*.

Firstly, *Dickinson* does not teach or suggest a dry powder composition in which the lactose particles have a specific size distribution. *Dickinson* teaches aerosol compositions comprising, in addition to medicament particles of 0.05 to 11 μm in diameter and lactose particles having a median volume diameter of 15 to 200 μm , a liquid propellant. The Examiner has not provided any reason why a person skilled in the art would have modified *Dickinson* to eliminate the liquid propellant to arrive at a dry powder composition.

Secondly, *Dickinson* does not teach or suggest compositions in which the lactose particles have a specific size distribution. In particular, *Dickinson* does not teach or suggest compositions that both have a VMD of between about 70 and

about 120 microns, and contain a certain proportion of lactose particles of less than 5 microns in diameter, e.g., up to 25% (claim 1), between 6.5 and 24.5% (claim 7), and 8.0-24% (claim 13). Instead, *Dickinson* teaches a composition in which the lactose particles are characterized by a median diameter or a sieved diameter in a certain range, e.g., about 90-125 μm , 45-65 μm , less than 38 μm , and less than 10 μm (See, e.g., Table 1 of *Dickinson*). *Dickinson* does not teach or suggest any desirability or advantage of a composition having the specific size distribution of lactose particles as claimed in the present invention. The Examiner has not provided any reason why a person skilled in the art would have selected such size distribution of lactose particles.

The Office Action contends that although *Dickinson* does not teach up to 96% by weight of lactose particles having a particle size of less than 150 μm or up to 25% by weight of lactose particles having a particle size of less than 5 μm , the determination of particular concentrations of particle sizes is within the skill of the ordinary worker as part of the process of normal optimization to achieve the dry powder of the presently claimed composition. However, "[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." *MPEP*, 8th Ed., Rev. 5, Aug. 2006, at 2100-71. The Office Action has not provided any evidence, either in *Dickinson* or knowledge otherwise generally available in the art, that a person skilled in the art would have recognized that the inclusion of a certain proportion of fine lactose particles of less than 5 μm in diameter is result-effective, and that the

inclusion of up to 25% of such fine lactose particles is desirable.

To the contrary, *Dickinson* appears to teach that lactose particles having small diameters such as those having a diameter of less than 10 microns are undesirable. For example, *Dickinson* teaches a lactose composition having particles of less than 10 μm (See, *Dickinson*, col. 10-11, Example H). According to *Dickinson*, the lactose composition of Example H had a median particle diameter of about 2.5 to 3.0 μm (see, *Dickinson* at col. 10, lines 58-60). However, *Dickinson* teaches that Example H showed poor dispersion quality (see, *Dickinson* at col. 11, lines 26-34), exhibited aggregates which could not be dispersed by hand held shaking (see, *Dickinson* at col. 11, lines 32-34), and poor suspension properties (see, *Dickinson* at col. 11, Table 1, last column). See also *Eau of Dispersion*, Extent of Aggregation, and Suspension Quality ratings for Example H in Table I. Thus, a person skilled in the art would not have been motivated by *Dickinson* to optimize the composition to include up to 25% of such fine lactose particles.

In addition, *Dickinson* teaches that the size of its particles is selected based in part on the solubility of the particles in the liquid propellant (See, *Dickinson*, col. 7, lines 5-19). The presently claimed invention, on the other hand, relates to a dry powder composition which does not contain a liquid propellant. In view of this, the difference between the claimed invention and *Dickinson* is not merely the optimization of particular concentrations of particle sizes. In order to arrive at the presently claimed invention, a person having ordinary skill in the art would not only have to stop the combination of the intermediate dry powder composition with a propellant and investigate the intermediate composition, but

also have to determine the lactose size distribution where solubility is not a factor.

The Office Action further contends that *Dickinson's* intermediate composition prior to combining with a liquid propellant reads on the claimed composition (see, the Office Action, page 3, last paragraph). Applicant respectfully submits that the Examiner has acknowledged in a previous section of the Office Action that *Dickinson* does not teach that up to 96% by weight of lactose particles have a particle size of less than 150 μm or up to 25% by weight of lactose particles have a particle size of less than 5 μm . Thus, *Dickinson's* intermediate composition does not read on the claimed composition.

Nor does *Dickinson's* intermediate composition render the claimed composition obvious. According to *Manual of Patent Examination Procedure*, if the prior art merely discloses compounds as intermediates in the production of a final product, one of ordinary skill in the art would not have been motivated to stop the reference synthesis and investigate the intermediate compounds with an expectation of arriving at claimed compounds which have different uses (*MPEP* 8th ed., rev. 5, Aug. 2006, at page 2100-157). In the present case, *Dickinson* teaches that the size of its particles is selected based in part on the solubility of the particles in the propellant (See, *Dickinson*, col. 7, lines 5-19). A person of ordinary skill in the art would not have stopped the combination of the intermediate composition with a liquid propellant and investigated the particle sizes of the lactose particles in the intermediate composition with an expectation of arriving at a dry powder composition not for use in conjunction with the liquid propellant, much less a dry powder composition having a lactose size distribution as claimed.

In view of the foregoing, Applicant respectfully submits that *Dickinson* does not render the presently claimed invention obvious. Withdrawal of the § 103(a) rejection over *Dickinson* is respectfully requested.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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